

Attorney Docket No.: 2870/155



PATENT

#15
P3/5/02

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: Shah, et al.

Serial No.: 09/324,182

Group Art Unit: 1615

Filed: June 2, 1999

Examiner: Pulliam, Amy

For: Non-Tacky Mascara Composition

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RESPONSE PURSUANT TO 37 CFR 1.111

The Assistant Commissioner of Patents and Trademarks

Washington, D.C. 20231

Dear Sir:

In the Examiner's Office Action dated October 10, 2001, Claims 1, 2, 7-19, 21, 22, 24 and 25 are rejected under 35 U.S.C. §102(b) as being anticipated by Pastour et al. (U.S. Pat. No. 5,523,091, hereinafter referred to as "the Pastour reference") and Claims 1-30 are rejected under 35 U.S.C. §103 as being unobvious in light of the Pastour reference. The compositions of the present invention comprise a substantially whole processed fruit or vegetable extract and this is not disclosed by the Pastour reference for the reasons explained below. Specifically, at page 3, lines 24 to 28, the preparation of the extract, as used in the present specification, is provided. The specification states expressly that the constituents of the fruit or vegetable are not filtered, at page 3, lines 26 to 28. The whole fruit or vegetable can be ground, liquefied, pressed or processed using other similar methods such that the whole processed plant, including the pulp and skin, is dispersible in silicone oil. The ability to perform these processing techniques are well within the knowledge of one of ordinary skill in the art, and it is, therefore, not necessary to elaborate thereupon in the specification. *S3 Inc. v. nVIDIA Corp.*, 59 USPQ2d 1745, 1749-50 (CAFC 2001). Other than the seeds, no part of the plant is removed or separated from the extract. A prior art reference fails to anticipate if it does not disclose each and every element of the claimed invention, and if the missing element is not inherent in the prior art reference. *In re Robertson*, 49 USPQ2d 1949, 1951 (CAFC 1999)(citation omitted). To establish inherency, the extrinsic evidence "must make clear that the missing element is necessarily present in the subject matter described in the prior art reference, and that it would be recognized by those of ordinary skill in the art." *Id.* (citing *Continental Can Co. v. Monsanto Co.*, 948 F.2d 1264, 1268, 20 U.S.P.Q.2d 1746, 1749 (Fed. Cir. 1991)). The Pastour reference fails to disclose the extract of the present invention.

Novelty:

Evidence that the extract referred to in the Pastour reference is not the same extract referred to in the present specification lies within the understanding that one of ordinary skill in the art has of the meaning of the word "extract" as it used in the Pastour reference in comparison with the substantially whole processed fruit or vegetable extract described in the present specification. The disclosure of plant extracts in the Pastour reference, which has been previously explained in Applicants Preliminary Amendment of August 3, 2001, pp. 5 to 6, is not in isolation; but, rather is in the context of being the source of an active principle. Specifically, at column 5, line 65 to column 6, line 4, the Pastour reference states, "[t]he aqueous phase can also contain adjuvants . . . It can also comprise active principles such as plant extracts . . ." The Pastour reference does not disclose the incorporation of plant extracts, *per se*, but rather, it discloses an active principle which can be a plant extract.

The Examiner notes that the Pastour reference does not require filtration; but, it is not necessary for the Pastour reference to restate the obvious. As it will be demonstrated below, filtration is a specific extraction technique used to purify an extract and obtain the active principles contained therein. In support of this basic principle of analytical chemistry, a comment by Tibotec Pharmaceuticals, Ltd. ("Tibotec"), in response to an FDA guidance document, entitled Guidance for Industry Botanical Drug Products is illustrative. The comment substantiates that further purification of an extract yields an extract of the active principles. The disclosure in the Pastour reference of an active principle such as a plant extract is sufficient for one of ordinary skill in the art to understand the application of filtration to obtain the active principle. This is evidenced by section 2.3, *Purification* of the comment wherein it describes the final purification of an extract by filtration to produce the purified extract containing active compounds. Thus, it can be seen that one of ordinary skill in the art knows and understands that a purified extract is produced by filtration and the end product is an extract containing active principles.

The comment by Tibotec also demonstrates another concern of the Examiner, and that is an extract is not the same as the substance, typically a plant or botanical, from which it is derived. In section 2.1 of the comment, entitled *Extraction*, the author of the comment describes an extraction of dried and milled plant leaves with ethanol. Clearly, the extract is not the plant material used to produce the extract as indicated by the next section 2.2, entitled *Initial Purification*, wherein it states "[t]he ethanolic botanical extract is . . . purified . . ." The botanical extract referred to is the product of the extraction process described in preceding section 2.1, *Extraction*. This demonstrates that one of ordinary skill in the art clearly understands that an extract derived from a plant material is not the same as the plant material.

Next, Applicants submit herewith a copy of a publication, "l'Ami des ingrédients naturels", April 2001, Nr. 27, to further demonstrate the understanding that one of ordinary skill in the art would have about extracts. In the publication, cosmetic actives are defined to be molecules that are extracted from plants, and are not the same as the plants from which they are extracted. First, at page 1, of the l'Ami publication, it is explained that molecules that are extracted are called cosmetic actives. Further, at page 2 of this publication, it is noted that molecules are used as cosmetic active principles under the form of extracts. Finally, extraction techniques are, as described at page 3, of the l'Ami publication, designed to optimize the yield of the active material from the plant, and to obtain the active principle, yielded from the plant, in a stable and usable form. It is clear from this publication that one of ordinary skill in the art understands that the extract containing the active principle is obtained by extraction techniques applied to the plant and is not the plant, *per se*.

Applicants also provide examples of extracts defined by the Food and Drug Administration ("FDA") as flavorings, additives, and substances. In each example the extract is taken from a whole plant, fruit, vegetable, or the like. For example, at page 10, vanilla extract is an aqueous ethyl alcohol solution of the sapid and odorous principles extractable from vanilla beans. Indeed, vanilla extract is not vanilla beans, and a disclosure of vanilla extract is not a disclosure of vanilla beans. One of ordinary skill in the art readily understands that an ice-cream recipe disclosing vanilla extract and cream, *inter alia*, is not a disclosure of vanilla beans and cream. Anyone understands that the results will be different. One produces smooth and delicious vanilla ice cream and the other produces a frozen cream product with vanilla beans in it. According to the Examiner, because the Pastour reference discloses plant extracts, without a requirement for filtration, the Pastour reference also discloses the addition of vanilla beans to its compositions. First of all, this is a misrepresentation of the disclosure in the Pastour reference because the Pastour reference discloses active principles such as a plant extract. And, even if the Pastour reference disclosed plant extracts, *per se*, one of ordinary skill in the art would not, based on the Pastour reference, understand this to mean the substantially whole processed plant from which the extract is derived.

Finally, Applicants submit a press release by ExtractsPlus, January 15, 1998, as it is recognized therein that confusion over the definition of a botanical extract is the result of greater or lesser degree of accuracy exercised when using the term "plant extract." As an example, it is stated in the press release that there "may be confusion between the pressed, dried juice of a plant and the extracts of the plant." In addition, the comment discusses the role of fillers in relation to extracts in section 5. Amount of filler in powdered extracts . . . Finally, but most importantly, this press release states,

**AN EXTRACT BY DEFINITION CANNOT CONTAIN ALL THE COMPONENTS
OF THE RAW HERB.**

Therefore, this press release and the other previously reviewed documents prove not only that the substantially whole processed extract of the present invention is not the plant extract of the Pastour reference as understood by one of ordinary skill in the art; but, that a requirement of filtration is inherent to the very essence of what an extract is and what it means to one of ordinary skill in the art, especially an extract containing active principles

The substantially whole processed extract of the present invention, approaches one end of the spectrum, namely, as described in the press release, the raw fruit or vegetable (but is just shy of the raw material because the extract of the present invention does not contain seeds), and is, therefore, substantially opposite the Pastour plant extract known and understood by one of ordinary skill in the art at the other end of the spectrum. The Pastour reference does not need to disclose a filtration requirement, as this would be redundant. It discloses all that is needed -- an active principle such as a plant extract, and thus, fails to disclose the substantially whole processed fruit or vegetable extract of the present invention. Therefore, the Pastour reference fails to disclose the present invention, and the Examiner's novelty rejection based on this reference must be withdrawn.

Non-Obviousness:

The Examiner asserts that the Pastour reference renders the present invention obvious. The Examiner admits that the Pastour reference does not teach the amounts of extract, the specific natural non-plant fiber, and the specific surfactant, but the Examiner believes that all of these limitations would be routinely determined by one of ordinary skill in the art based on the teachings of the Pastour reference. However, Applicants previously noted, in the Preliminary Amendment of August 3, 2001, that the functional difference between the Pastour reference and the present invention is the incorporation of the plant extract in the aqueous phase of the Pastour compositions contrasted with the substantially whole processed fruit or vegetable extract of the present invention that is dispersed in silicone oil. In addition, to the differences between the plant extract of the Pastour reference and the substantially whole processed fruit or vegetable extract of the present invention, the Pastour reference teaches that its extract is part of the aqueous phase. If this teaching is applied using the extract of the present invention, one of ordinary skill in the art would expect the tackiness of the water phase to be significantly increased, and therefore, the Pastour reference fails to teach or suggest the non-tacky composition of the present

invention, in addition to not teaching the incorporation of the substantially unfiltered whole processed fruit or vegetable extract, as explained above in the response to the novelty rejection. Applicants previously explained this and the Examiner has not responded to this argument. M.P.E.P. 707.07(f)

The achievement of the present invention is surprising as mentioned in Applicants' previous response of January 2, 2001, and also in the Preliminary Amendment of August 3, 2001. The ability of the mascara of the present invention to perform as well as traditional mascara is unexpected because the extract of the present invention contains nearly all of the components of the fruit or vegetable which would be expected to cause the mascara to perform poorly. It is not expected that a mascara formula containing raw, substantially unfiltered whole fruit and vegetable extracts could achieve desirable qualities at all, nonetheless to perform comparably to conventional mascaras that are formulated to achieve these qualities with synthetically derived ingredients. A response to this argument, made previously by Applicants, has not been given. Despite conventional wisdom, the mascara of the present invention containing unfiltered substantially whole processed fruit or vegetable extract (i.e., containing sticky sugar, gummy and tacky pulp) is non-tacky and comparable to conventional mascaras.

Applicants maintain that the claims of the present application satisfy the requirements of 35 U.S.C. §103(a) because the Pastour reference fails to teach or suggest a substantially unfiltered whole processed fruit or vegetable extract dispersed in silicone oil. Thus, Applicants request that this rejection be withdrawn.

CONCLUSION

Applicants believe that the present claims are patentable over the cited prior art reference. Accordingly, the claims, as amended, are believed to be in condition for allowance, and issuance of a Notice of Allowance is respectfully solicited.

Respectfully submitted,

Date January 9, 2002



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